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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,691	09/15/2000	George Wu	PT1443001	6763

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IVOR M. HUGHES, BARRISTER & SOLICITOR,  
PATENT & TRADEMARK AGENTS  
175 COMMERCE VALLEY DRIVE WEST  
SUITE 200  
THORNHILL, ON L3T 7P6  
CANADA

EXAMINER

WILLIS, MICHAEL A

ART UNIT	PAPER NUMBER
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DATE MAILED: 02/26/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/593,691

Applicant(s)

WU ET AL.

Examiner

Michael A. Willis

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-82 is/are pending in the application.
- 4a) Of the above claim(s) 49-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-47 is/are rejected.
- 7) ☒ Claim(s) 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response of 20 November 2002 is entered. Any previously stated rejections that are not restated below are hereby withdrawn.

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 38-48) in Paper No. 10 is acknowledged. Claims 49-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's election without traverse of N-acetylglucosamine as the species of at least one amino sugar, sodium as the species of electrolyte, and glucose as the species of at least one additional agent, respectively, in Paper No. 10 is acknowledged. Claims 38-48 are examined as they read on the elected species.

Applicant's comments with respect to rejoinder are acknowledged. For office policy with respect to rejoinder, see MPEP 821.04.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 15 July 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,083,935 has been reviewed and is accepted. The terminal disclaimer has been recorded. In response to the filing of the terminal disclaimer, the double patenting rejection is withdrawn.

### ***Abstract***

In the preliminary amendment of 15 June 2000, paper #3, applicant directs the office to "Please cancel the abstract presently on file and replace it with the new abstract submitted herein." However, in reviewing the case file, the examiner could only find a single abstract. It is unclear if this abstract is the original or the replacement. The abstract of record reads as follows: "The present invention relates to a peritoneal dialysis solution comprising at least one amino sugar in an effective amount sufficient to create an osmotic pressure to effect the removal of water by diffusion from the patient's blood across the peritoneal membrane into the solution. In one embodiment the at least one amino sugar is selected from the group consisting of acetylated amino sugars, preferably N-acetylglucosamine, deacetylated amino sugars and combinations thereof."

If the above abstract is applicant's intended abstract, no action is required on the part of applicant. If the above abstract should have been replaced with a different abstract according to the preliminary amendment, the examiner respectfully requests that applicant resubmit the desired abstract.

### ***Specification***

The preliminary amendment filed 15 June 2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

"bicarbonate" as stated in claims 48, 59, 70, and 82 and any dependent claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

While claims 59, 70, and 82 are withdrawn from examination as being directed to a non-elected invention, they remain part of the disclosure until cancelled. Therefore, they should be either cancelled or amended to remove the term bicarbonate. Applicant's removal of the term "bicarbonate" from claims 45, 56, 67, and 79 in paper #6, submitted 15 July 2002 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

Claim 48 is rejected under 35 USC 112, first paragraph, for reasons as previously stated due to the term "bicarbonate". This is a "new matter" rejection. Applicant's removal of the term "bicarbonate" from claims 45, 56, 67, and 79 in paper #6, submitted 15 July 2002 is acknowledged. However, the term "bicarbonate" in claim 48 appears to have been overlooked. The rejection can be obviated by removal of the term.

### ***Response to Arguments***

The rejection of claims 38-44 under 35 USC 103(a) with respect to Seyffart et al (US 4,879,280) and Breborowicz et al (EP 0555 087 A1) in view of "Textbook of Biochemistry" is withdrawn. Applicant's arguments directed to the elected species of N-acetylglucosamine are convincing. In other words, applicant's argument that one of

Art Unit: 1617

ordinary skill in the art would not look to N-acetylglucosamine from Breborowicz's teaching of oligosaccharide degradation products of hyaluronic acid is convincing.

However, it is noted that applicant's statements with respect to the claimed oligomers having the "same repeating monosaccharide" is not supported by the specification.

Furthermore, such a feature is not claimed. As such, the references may be re-considered if examination is extended to aminosugars beyond the elected species of N-acetylglucosamine.

Claim 48 is rejected under 35 USC 103(a) as being unpatentable over Kubo et al (JP 11-71273-A) for reasons as stated previously. Applicant's argument that the rejection is rendered moot by the removal of the term "bicarbonate" is not convincing in that the term "bicarbonate" is still present in the claim.

The following new grounds of rejection are made:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Pecht et al (US Pat. 4,996,296). Pecht discloses a 5% N-acetylglucosamine solution in aqueous buffer (see col. 18, lines 45-50 and col. 16, lines 20-25). The preamble and the

Art Unit: 1617

intended use of the instant claims are not given patentable weight. The limitations of the instant claims are the presence of N-acetylglucosamine as the elected species of amino sugar in an effective amount, which is claimed as ranging from about 0.5% to about 5% (w/v). The reference meets these limitations.

Claims 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Speck et al (US Pat. 4,870,061). Speck discloses aqueous solutions of N-acetylglucosamine having a concentration of 5 to 55 mg/mL, corresponding to 0.5 to 5.5% (w/v) (see col. 4, lines 50-52). The preamble and the intended use of the instant claims are not given patentable weight. The limitations of the instant claims are the presence of N-acetylglucosamine as the elected species of amino sugar in an effective amount, which is claimed as ranging from about 0.5% to about 5% (w/v). The reference meets these limitations.

### ***Claim Rejections - 35 USC § 103***

Claims 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speck et al (US Pat. 4,870,061).

The instant claims are directed to compositions comprising N-acetylglucosamine, sodium in an effective amount, and glucose, where the N-acetylglucosamine and glucose together are present at a concentration of about 0.5 to about 5.0% (w/v). The specification at page 7 states that "sodium is usually included at a concentration slightly lower to that found in plasma, or 132-137 mM/L".

Speck teaches aqueous solutions of N-acetylglucosamine having a concentration of 5 to 55 mg/mL, corresponding to 0.5 to 5.5% (w/v) (see col. 4, lines 50-52). Speck further teaches that the osmolality of the solutions has to be adapted to the physiological osmotic pressure by addition of NaCl or glucose (see col. 4, lines 50-60). The reference lacks examples with both glucose and sodium.

The missing ingredients of glucose and sodium have art-recognized suitability for the intended purpose of formulating a composition adapted to physiological osmotic pressure. The selection of a known material based on its suitability for its intended use has been determined to be *prima facie* obvious. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945); *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960); and MPEP 2144.07. Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Speck by the use of glucose and sodium to modify the osmolality in order to formulate a composition for physiological administration. The motivation for the change comes from the teaching by Speck that "the osmolality of the solutions...has to be adapted to the physiological osmotic pressure by addition of for instance NaCl or glucose".




**Conclusion**

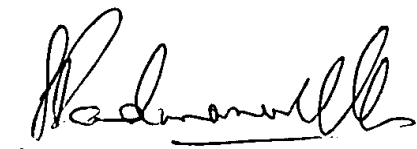
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on alt. Mondays and Tuesday to Friday (9am-6:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

  
Michael A. Willis  
Examiner  
Art Unit 1617

maw  
February 13, 2003

  
SREENI PADMANABHAN  
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